

REMARKS

1. Preliminary Remarks

a. Status of the Claims

Claims 26, 31, 33, and 35-37 are pending in this application. All these claims are amended. Applicant respectfully requests entry of the amendments and remarks made herein into the file history of the application. Upon entry of the amendments, claims 26, 31, 33, and 35-37 will be pending and under active consideration.

b. Amendments to the Claims

Support for the amended claims can be found at paragraph 0035 of the application as originally filed. Applicant notes that the amendments to claims 31, 33, 36, and 37 are made for clarification purposes only, and do not change the scope of these claims. Applicant further notes that the amendments to claims 26 and 35 are made to relate part (b) to a DNA encoding the RNA of part (a), because SEQ ID NOs: 4204050 and 117937 are RNA sequences.

c. Objection to the Specification

On page 2 of the Office Action, the Examiner objects to the specification because it refers to Tables 1-14 at paragraph 0027, but it allegedly does not contain any tables labeled 1-14. The Examiner asserts at page 2 of the Office Action that the incorporation by reference to Tables 1-14 at paragraph 0027 is improper. The Examiner further asserts at page 5 of the Office Action that the incorporation is improper under MPEP § 608.01(p), because Tables 1-14 contain essential material, and such material can only be incorporated by reference to a U.S. patent or published patent application. Applicant submits that the rule discussed in MPEP § 608.01(p)—37 C.F.R. § 1.57—is inapplicable to the incorporation of Tables 1-14. Rather, 37 C.F.R. § 1.57 is directed to the incorporation by reference of publications separate from the instant application, and has nothing to do with the incorporation of parts of the application itself. *See* 37 C.F.R. § 1.57(a).

Instead, the issue of incorporating Tables 1-14 by reference falls under the patent rule provision 37 C.F.R. § 1.52(e), as this section governs electronic documents that are part of a patent application. This rule allows an applicant to submit any individual table if the table is over 50 pages in length or if the total number of pages of all the tables of the application exceed 100 pages in length. *See* 37 C.F.R. § 1.52(c)(iii). Applicant submits that Tables 1-14 exceed 100 pages in length, and Applicant was therefore allowed to submit the tables via compact disc under 37 C.F.R. § 1.52(c). The Patent Office has these compact discs in its possession—as shown in acknowledged receipt by

the U.S. Patent Office of compact discs at the time of filing. *See* Appendix A. Additionally, the Examiner admits that he has attempted to view the application tables supplied on the compact discs. *See* Instant Office Action, at page 5.

Because Applicant submitted the tables via compact disc, their incorporation by reference in a separate paragraph in the specification was necessary. *See* 37 C.F.R. § 1.57(c)(5). As the Examiner admits, paragraph 0027 of the specification includes the required incorporation by reference. *See* Instant Application, at pages 2 and 5, *and* Instant Specification, at paragraph 0027. Accordingly, Applicant has complied with requirements for submitting Tables 1-14 on compact disc. Consequently, **these tables are part of the application as filed**. *See* MPEP § 608.05 (“The compact disc(s) is considered part of the original disclosure by virtue of its inclusion with the application on the date the application is accorded a filing date. The incorporation by reference statement of the material on the compact disc is required to be part of the specification...”). In view of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdraw the objection to the specification.

d. Objection to the Claims

On page 3 of the Office Action, the Examiner objects to claims 31, 33, 36, and 37 under 37 C.F.R. § 1.75(c) for allegedly being in improper dependent form. The Examiner asserts that claim 26 uses closed language in describing an isolated nucleic acid consisting of a nucleic acid sequence, and that as a result, the vector of claim 31 comprising the nucleic acid of claim 26 improperly adds matter that is not accounted for in claim 26. Claim 31 is related to a vector comprising a nucleic acid of claim 26. Likewise, claim 36 is related to a vector comprising a nucleic acid of claim 35, and claims 33 and 37 relate to probes comprising a nucleic acid of claim 26 and 35, respectively. Claims drawing their dependency from an independent claim must contain all the limitations of the independent claim and can only further limit the subject matter of the independent claim. *See* 37 C.F.R. § 1.75(c). As exemplified below, the Examiner, however, has misconstrued the scope of vector claims 31 and 36 and probe claims 33 and 37 by impermissibly expanding the scope of independent nucleic acid claims 26 and 35 beyond their limitations and therefore, in turn, expanding the scope of the vector and probe claims beyond their permissible limitations.

Specifically, the Examiner appears to contend that the vector may comprise long stretches of DNA encoding the nucleic acid of claims 26 and 35 along with any other additional DNA sequences. This interpretation is in stark contrast to the Examiner's correct acknowledgment that the scope of independent claims 26 and 35 is directed to nucleic acids consisting of the sequences

set forth in these claims. *See* Instant Office Action at 3, lines 5 and 10. Accordingly, if dependent vector claim 31, for example, must contain the limitation of claim 26, the vector must comprise an insert consisting of the nucleic acid of claim 26 wherein the vector does not comprise any other inserts but the nucleic acid of claim 26. Of course, the vector of claim 31 would contain unrecited elements familiar to one of skill that allow the vector to properly function (*e.g.*, origin of replication, *etc.*) or have a particular characteristic (*e.g.*, antibiotic resistance, multiple cloning site, *etc.*), but these unrecited elements would not be sequences within the insert of claim 26. However, the vector of claim 31 would not include an insert with additional sequences such as the 229,287 extraneous nucleotides of GenBank X17403.1 (as cited from WO/200257437 by the Examiner below), which allegedly harbors SEQ ID NO: 4204050, which further comprises SEQ ID NO: 117937. Such an insert of GenBank X17403.1 would not be within the scope of vector claim 31 because the insert would be outside the scope of claim 26. Accordingly, claim 31 contains all the limitations of claim 26 and does not impermissibly expand its scope to include unrecited elements, and in fact, limits the vector insert to nucleic acids of claim 26.

Nevertheless, in order to expedite prosecution, claims 31, 33, 36, and 37 are amended to clarify that the claimed vectors and probes may not comprise a viral insert that falls outside the scope of claims 26 or 35. Applicant submits that the scope of the claim is not changed by the amendment. Applicant notes that the scope of instant claims 31 and 33, and of claims 36 and 37 is not limited to including only one copy of an insert consisting of a nucleic acid falling within the scope of claims 26 and 35, respectively. Nor is the scope of instant claims 31 and 33, or of claims 36 and 37 limited to one particular nucleic acid that falls within the scope of claims 26 and 35, respectively. In view of the foregoing, Applicant submits that vector claim 31 properly includes all the limitations of claim 26 by only requiring an insert consisting of the nucleic acid of claim 26. Claim 33 likewise properly includes all the limitations of claim 26, and claims 36 and 37 include all the limitations of claim 35. Applicant therefore respectfully requests that the Examiner reconsider and withdraw the objections to the claims.

2. Patentability Remarks

a. 35 U.S.C. § 112, first paragraph

On page 4-6 of the Office Action, the Examiner rejects claims 26, 31, 33, and 35-37 under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the enablement requirement. The basis of the Examiner's rejection is based on his erroneous assertion that Tables 8 and 9 were not intended to be part of the specification as filed because these tables were supplied on compact discs

and were improperly incorporated by reference at paragraph 0027 of the specification as originally filed. *See* Instant Office Action, at pages 4 and 5. As described above, compact discs received with the application at the time of filing are part of the application. *See* MPEP § 608.05, *supra*. In contrast to the Examiner's assertion, not only is Applicant's incorporation of the tables by reference in specification proper, but it is required. Applicant submits that the tables included on the compact discs submitted with the application are part of the application, and consequently, contrary to the Examiner's allegation, the application is not missing any essential material. In view of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 112, first paragraph.

b. 35 U.S.C. § 102

On pages 6 and 7 of the Office Action, the Examiner rejects claims 31 and 36 under 35 U.S.C. § 102(b) as allegedly being anticipated by Ghazal, *et al.* (WO/200257437; "Ghazal"). The sequence taught by Ghazal (GenBank AX686187.1) is 229,354 nucleotides in length and includes a 67 nucleotide-long stretch that allegedly is identical to SEQ ID NO: 4204050, which comprises SEQ ID NO: 117937. The Examiner asserts that Ghazal teaches vectors comprising SEQ ID NO: 4204050 and SEQ ID NO: 117937. As described above, the scope of independent claims 26 and 35 is directed to the nucleic acid consisting of the sequences respectively set forth in these claims. Dependant vector claim 31 or 36 comprises the insert consisting of the nucleic acid of claim 26 or 35, wherein the vector does not comprise any other inserts but the nucleic acid of claim 26 or 35. The vector of claim 31 or 36 would contain unrecited elements to allow the vector to function or have a particular characteristic, but would not include an insert with any other additional sequences from claims 26 or 35, including any sequence from the 229,287 extraneous nucleotides of GenBank X17403.1. Accordingly, the scope of the claims excludes GenBank AX686187.1, and therefore are not anticipated by Ghazal. In view of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 102(b).

c. 35 U.S.C. § 103

(1) Claims 35 and 37

On pages 7-9 of the Office Action, the Examiner rejects claims 35 and 37 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ghazal in view of Buck, *et al.* (BioTechniques, 1999;27:528-36; "Buck"). The Examiner alleges that Ghazal teaches a vector comprising an insert consisting of instant SEQ ID NO: 4204050 and of SEQ ID NO: 117937. The Examiner contends that one of skill would reasonably expect that a sequencing primer synthesized essentially

anywhere along a give sequence of interest would perform adequately to yield sequence data. Instant Office Action, at page 9. The Examiner thus asserts that it was obvious to one of skill that primers were required to obtain the sequence taught by Ghazal, that it was obvious to make primers of the same length as SEQ ID NO: 117937, and that primers can be considered to be probes. *Id.* at pages 7-8. Applicant respectfully disagrees.

As discussed above, the insert of Ghazal is excluded by the scope of the instant claims. Nevertheless, Applicant submits that even if the primers/probes cited by the Examiner include SEQ ID NO: 117937 or its complement, this is not sufficient by itself to establish a *prima facie* case of obviousness. *See* MPEP § 2144.08.II (“The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness”). Considering the massive size of the genus of sequences taught by Ghazal in view of Buck, there is simply no way for one of skill to envisage the claimed subgenus of nucleic acids within the genus. *See* MPEP § 2144.08.a.4.(a). The Ghazal insert is 229,354 nucleotides in length. Buck teaches design and generation of primers that are 17 to 24 nucleotides in length. Buck, at abstract. Accordingly, the group of 17 to 24 nucleotide-long primers cited by the Examiner that are capable of binding anywhere along the Ghazal insert encompasses at least 1,834,676 different sequences. The claimed nucleic acid related to SEQ ID NO: 117937 is but one subgenus within this massive genus of primers. There is no teaching or suggestion in Ghazal or Buck to lead one of skill to select a primer that is related to a miRNA, or any other sequence capable of regulating a gene transcript in *trans*, as is provided in the instant claims. The same holds true for probes—there is nothing in any of the art cited by the Examiner to lead one of skill to select a probe related to SEQ ID NO: 117937 from among the over 1.8 million possible sequences taught by Ghazal in view of Buck.

(2) Claims 26 and 33

On pages 7-9 of the Office Action, the Examiner rejects claims 26 and 33 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ghazal in view of Hogan (US 5,541,308; “Hogan”). The Examiner asserts that Ghazal teaches a vector comprising a sequence consisting of SEQ ID NO: 4204050. The Examiner further asserts that it was obvious to one of skill that parameters and objectives for probe generation were well known in the art at the time of filing, as evidenced by Hogan, and therefore that it would have been obvious to generate a probe of any length corresponding to any fragment of the CMV genome, including the portion of SEQ ID NO: 4204050 disclosed by Ghazal. Applicant respectfully disagrees.

As discussed above, the Ghazal insert is excluded by the scope of the instant claims. Nevertheless, Applicant submits that even if the probes cited by the Examiner include SEQ ID NO: 4204050, this is not sufficient by itself to establish a *prima facie* case of obviousness. *See* MPEP § 2144.08.II, *supra*. Considering the massive size of the genus of sequences taught by Ghazal in view of Hogan, there is simply no way for one of skill to envisage the claimed subgenus of nucleic acids within the genus. *See* MPEP § 2144.08.a.4.(a). The Ghazal insert is 229,354 nucleotides in length. According to the Examiner, Hogan teaches that probes may be 15 to 50 bases in length. Accordingly, the group of probes of 15-50 nucleotides in length cited by the Examiner that are capable of binding anywhere along the Ghazal insert encompasses **at least 8,255,610 different sequences**. The claimed nucleic acid related to SEQ ID NO: 4204050 is but one subgenus within this massive genus of probes. There is no teaching or suggestion in Ghazal or Hogan to lead one of skill to select a 67 nucleotide-long probe that is related to a miRNA, or any other sequence capable of regulating a gene transcript *in trans*, as is provided in the instant claims, from among the over 8 million probes these references teach. In view of the foregoing, Applicant respectfully requests that the Examiner reconsider and withdraw the claim rejections under 35 U.S.C. § 103(a).

3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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APPENDIX A

ARTIFACT SHEET

Enter artifact number below. Artifact number is application number + artifact type code (see list below) + sequential letter (A, B, C ...). The first artifact folder for an artifact type receives the letter A, the second B, etc.. Examples: 59123456PA, 59123456PB, 59123456ZA, 59123456ZB

10709738 SA

Indicate quantity of a single type of artifact received but not scanned. Create individual artifact folder/box and artifact number for each Artifact Type.

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CD(s) containing:

computer program listing

Doc Code: Computer

pages of specification

and/or sequence listing

and/or table

Doc Code: Artifact

content unspecified or combined

Doc Code: Artifact

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Artifact Type Code: P

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Artifact Type Code: S

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Artifact Type Code: U

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Stapled Set(s) Color Documents or B/W Photographs

Doc Code: Artifact Artifact Type Code: C

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Microfilm(s)

Doc Code: Artifact Artifact Type Code: F

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Video tape(s)

Doc Code: Artifact Artifact Type Code: V

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Model(s)

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Bound Document(s)

Doc Code: Artifact Artifact Type Code: B

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Doc Code: Artifact Artifact Type Code X

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Other, description: _____

Doc Code: Artifact Artifact Type Code: Z